

Notice of Allowability

Application No.

10/070,387

Examiner

David J. Steadman

Applicant(s)

MIDOH ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 3/27/07.
2. ☒ The allowed claim(s) is/are 1, 13, 15 and 18.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of
Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Status of the Application

- [1] Applicant's amendment to the claims, filed on 3/27/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [2] Claims 1, 13, 15, and 18 are pending in the application (following the examiner's amendment as set forth below).

Examiner's Amendment to the Claims

- [3] An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Mr. Jay F. Williams on 6/15/07.

- [4] The application has been amended as follows:

[a] Please re-write claim 13 as follows:

13. A method for producing a protein having cyclo(D-lactyl-L-N-methyllleucyl-D-3-phenyllactyl-L-N-methyllleucyl-D-lactyl-L-N-methyllleucyl-D-3-phenyllactyl-L-N-methyllleucyl) (PF1022) synthetase activity, which comprises the steps of:
culturing a host cell transformed with a vector containing a nucleotide sequence under conditions suitable for protein expression, wherein the nucleotide sequence is selected from the group consisting of:

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(a) a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2 and (b) the nucleotide sequence of SEQ ID NO:1; and collecting the protein from the culture medium.

[b] Please add the following new claim:

18. A method for producing a protein having cyclo(D-lactyl-L-N-methyllleucyl-D-3-phenyllactyl-L-N-methyllleucyl-D-lactyl-L-N-methyllleucyl-D-3-phenyllactyl-L-N-methyllleucyl) (PF1022) synthetase activity, which comprises the steps of: culturing a host cell transformed with a vector containing a nucleotide sequence under conditions suitable for protein expression, wherein the nucleotide sequence is a nucleotide sequence that has at least 95% homology to the nucleotide sequence of SEQ ID NO:1 and which encodes a protein having PF1022 synthetase activity; and collecting the protein from the culture.

Reasons for Allowance

[5] As noted in the prior Office action, "a review of the translated foreign priority documents (translations filed on 21 June 2004 and 3 November 2004) suggests that the limitation of part (c) of claim 15 [as presented in the claim listing filed on 10/13/06], while apparently supported by the international application, is not supported by the foreign priority documents...the effective filing date of...claim 15 is considered to be the date of filing of the international application, *i.e.*, 7 September 2000. The reference of Weckwerth et al. indicates that the invention was known by others on 4 April 2000 (see

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23 July 2004 Office action at p. 8 for a discussion of determining the earliest public availability date of Weckwerth et al.), and as such, the reference is available as prior art under 35 U.S.C. 102(a)" (Office action mailed on 12/27/06 at pp. 3-4). In view of the instant amendment to claim 15 to delete part (c), the rejection under 35 U.S.C. 102(a) as being anticipated by Weckwerth et al. (*J Biol Chem* 275:17909; cited in the IDS filed March 06, 2002) is withdrawn.

It is noted that claim 13 also includes a limitation that does not appear to be supported by the foreign priority documents. However, in view of the respective Courts' holding in *In re Bell* 26 USQP2d 1529 (Fed. Cir. 1993) and *In re Deuel* 34 USPQ2d 1210 (Fed. Cir. 1995), the reference of Weckwerth et al. has not been applied in a prior art rejection of claim 13, particularly because the Weckwerth et al. reference fails to disclose sufficient information regarding the amino acid sequence of the isolated PFSYN polypeptide. The Court in *In re Deuel* stated: "[w]ritten in such a result-oriented form, claims 4 and 6 are thus tantamount to the general idea of all genes encoding the protein, all solutions to the problem. Such an idea might have been obvious from the *complete* amino acid sequence of the protein, coupled with knowledge of the genetic code, because this information may have enabled a person of ordinary skill in the art to envision the idea of, and, perhaps with the aid of a computer, even identify all members of the claimed genus. The Bohlen reference, however, only discloses a partial amino acid sequence, and thus it appears that, based on the above analysis, the claimed genus would not have been obvious over this prior art disclosure." Similarly, because the Weckwerth et al. reference fails to disclose *any* amino acid sequence information of

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the PFSYN polypeptide, the genus of nucleic acids having at least 95% homology (interpreted as meaning "identity") to SEQ ID NO:1 would not have been obvious to one of ordinary skill in the art at the time of the invention.

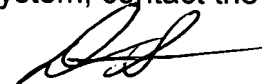
The examiner has found no teaching or suggestion in the prior art of record directed to the polypeptide of SEQ ID NO:2 or a method of recombinant production of SEQ ID NO:2 and variants thereof having PF1022 synthetase activity as encompassed by the claims. Therefore, the claimed invention is allowable over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
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